



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 13 2005

Discus Dental Incorporated  
C/O Mr. Alfredo J. Quattrone, Ph.D., DABT  
Responsible Third Party Official  
California Department of Health Services  
Food & Drug Branch  
P.O. Box 997 413  
Sacramento, California 95899-7413

Re: K051776

Trade/Device Name: Protégé Ultrasonic Insert Devices  
Regulation Number: 21 CFR 872.4850  
Regulation Name: Ultrasonic Scaler  
Regulatory Class: II  
Product Code: ELC  
Dated: June 22, 2005  
Received: July 1, 2005

Dear Dr. Quattrone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

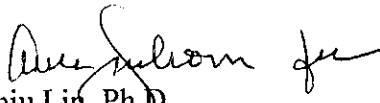
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K051776

**V. Indications for Use Statement**510(k) Number: K051776**Device Name:** Protégé Ultrasonic Insert Devices**Intended Use**

Protégé Ultrasonic Inserts, both 25KHz and 30KHz models, are intended to be used in the handpieces of any magnetostrictive ultrasonic scaler for dental cleaning and the removal of tenacious calculus deposits by application of an ultrasonic vibrating tip to the teeth.

Prescription Use XX  
Per 21 CFR Section 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Betz, DDS for Dr. Susan Runner  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K051776

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